4.0 510(k) Summary

OCT 16 2012

Submitter:
Wisconsin Pharmacal Company, LLC
US Agent for Polichem SA
1 Pharmacal Way
Jackson, WI 53037

Contact Person:
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Quality Assurance Manager
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(262) 677-7112

Date Submitted:

Proprietary Names:
Me Again® Long Lasting Vaginal Moisturizer and vH Essentials® Long Lasting Vaginal Moisturizer

Common Name:
Personal Lubricant

Classification Name:
21 CFR 884.5300 Lubricant, Patient, Vaginal, Condom
Product Code: NUC
Class: II
Review Panel: Obstetrics/Gynecology

Predicate Devices:

Device Name: Replens Long-Lasting Vaginal Moisturizer
510(k) Number: K101241
Product Code: NUC

Device Name: CVS Personal Lubricant & Moisturizer
510(k) Number: K062682
Product Code: NUC, MMS

Intended Use:

Long Lasting Vaginal Moisturizer is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of

intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Description of Device:

Long Lasting Vaginal Moisturizer is a non-sterile, non-greasy, water-based personal lubricant delivered in single-use, pre-filled vaginal applicators. Long Lasting Vaginal Moisturizer can be used daily to supplement the body's natural lubrication. Long Lasting Vaginal Moisturizer contains ingredients commonly found in cleared personal lubricants.

Technological Characteristics of the Device:

Long Lasting Vaginal Moisturizer is substantially equivalent to the identified previously cleared vaginal moisturizer predicates with respect to its design and materials, principles of operation, function, formulation, and intended use.

Summary of Performance Data:

Biocompatibility Testing: The following biocompatibility testing has been performed on Long Lasting Vaginal Moisturizer:

- Cytotoxic evaluation following the EN ISO 10993-5 rule
- Delayed hypersensivity test – Guinea-Pig Maximisation Test (GPMT) according to ISO 10993-10:2010
- Acute Vaginal Irritation – hybrid test
- Acute Systemic Toxicity – hybrid test

Stability Data: Stability data confirms a shelf life of 24 months for Long Lasting Vaginal Moisturizer.

Compatibility Testing: Recent condom compatibility testing conducted per ASTM D7661-10 demonstrates that Long Lasting Vaginal Moisturizer is not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Conclusion: Long Lasting Vaginal Moisturizer is substantially equivalent to its proposed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Polichem SA
% Mr. John Nygaard
Quality Assurance Manager
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OCT 16 2012

Re: K112217
Trade/Device Name: Me Again® Long Lasting Vaginal Moisturizer
vH Essentials® Long Lasting Vaginal Moisturizer
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: September 20, 2012
Received: September 24, 2012

Dear Mr. Nygaard:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K112217

Device Name: Me Again® Long Lasting Vaginal Moisturizer

Indications for Use:

Me Again® Long Lasting Vaginal Moisturizer is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112217

Indications for Use

510(k) Number: K112217

Device Name: vH Essentials® Long Lasting Vaginal Moisturizer

Indications for Use:

vH Essentials® Long Lasting Vaginal Moisturizer is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___X___ (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
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